

REMARKS

At the time the current Official Action was mailed, the Examiner rejected claims 1-13. Claims 1-20 are pending. Claims 1, 5, 8, and 11 have been amended. Claims 14-20 have been added. Reconsideration of the application in view of the remarks set forth below is respectfully requested.

Claim Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 1-13 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Applicant respectfully traverses this rejection. As suggested by the Examiner, the Applicant has amended independent claims 1, 5, 8, and 11 to include the recitation “using metrics applied to the pulse oximetry signal.” Accordingly, this rejection is moot and Applicant respectfully requests withdrawal of the 35 U.S.C. § 112, second paragraph, rejection of claims 1-13.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 3-5, 7-11, and 13 under 35 U.S.C. § 103(a) as being unpatentable over the Baker reference (U.S. Application No. 2002/0137994) in view of the Harada reference (US Patent No. 5,759,157); and claims 2, 6, and 12 as being unpatentable over the Baker reference in view of the Leon reference (US Patent No. 5,365,934). The Applicant respectfully traverses this rejection.

Legal Precedent

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish a *prima facie* case of obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). However, it is not sufficient to show that all the elements exist in the prior art, since a claimed invention composed of several elements may not be proved obvious merely by demonstrating each element was known, independently, in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* Specifically, there must be some articulated reasoning with a rational underpinning to support a conclusion of obviousness; a conclusory statement will not suffice. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Indeed, the factual inquiry determining whether to combine references must be thorough and searching, and must be based on *objective evidence of record*. *In re Lee*, 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002).

Rejection of Claims 1, 3-5, 7-11, and 13 based on Baker in view of Harada

In rejecting claims 1, 3-5, 7-11, and 13, the Examiner stated

Regarding claim 1, Baker discloses a method of determining a heart rate from a pulse oximetry signal comprising determining first and second heart rates from a pulse oximetry signal using first and second methods (paragraphs [0056]-[0057]), and using metrics to determine which heart rate to use (paragraphs

[0034], [0057], [01771]. Baker does not disclose applying the metrics to only the first heart rate, and using the first rate if the metrics indicate that it is reliable and using the second when the metrics indicate that the first heart rate is unreliable. Harada teaches a method of analyzing biosignals comprising evaluating the reliability of a first calculated result, and, based on that reliability determination, deciding whether to use the first calculated result or a second one (column 3, lines 44-48; column 5, lines 17-20), in order to minimize the number of required processing steps.

Regarding claim 5, Baker discloses a system comprising a first heart rate calculator that determines a heart rate from a pulse oximetry signal using a first method (paragraph [0056]), a second heart rate calculator that determines a heart rate from the pulse oximetry signal using a second method (paragraph [0057]), and an evaluator configured to evaluate the reliability of the signals using metrics and a selector that chooses a heart rate based on the reliability results (paragraphs [0057], [0177]). Baker does not disclose the evaluator applying the metrics to only the first rate, and using the first rate if it is reliable and using the second rate if the first is unreliable. Harada teaches a system for analyzing biosignals comprising an evaluator for determining the reliability of a first calculated result, and, based on that reliability determination, using a selector to decide whether to use the first calculated result or a second one (column 3, lines 44-48; column 5, lines 17-20), in order to minimize the number of required processing steps.

Regarding claims 8 and 10, Baker discloses a pulse oximetry system comprising a sensor adapted to provide a signal related to a physiological constituent (paragraphs [0035], [0052]) and a monitor adapted to process the signal to determine a pulse period, the monitor comprising software adapted to process the signal to determine a first pulse period using a first method (paragraph [0056]), software adapted to process the signal to determine a second pulse period using a second method (paragraph [00571]), and an evaluator configured to evaluate the reliability of the signals using metrics and a selector that chooses a heart rate based on the reliability results (paragraphs [0057], [0177]). Baker does not disclose the evaluator applying the metrics to only the first rate, and using the first rate if it is reliable and using the second rate if the first is unreliable. Harada teaches a system for analyzing biosignals comprising an evaluator for determining the reliability of a first calculated result, and, based on that reliability

determination, using a selector to decide whether to use the first calculated result or a second one (column 3, lines 44-48; column 5, lines 17-20), in order to minimize the number of required processing steps.

Regarding claim 11, Baker discloses a method of determining a heart rate in a pulse oximeter comprising determining a first pulse period from a pulse oximetry signal using a first method (paragraph [0056]), software adapted to process the signal to determine a second pulse period using a second method (paragraph [0057]), and an evaluator configured to evaluate the reliability of the signals using metrics and a selector that chooses a heart rate based on the reliability results (paragraphs [0057], 0177)). Baker does not disclose applying the metrics to the first pulse period, and using the first rate if it the metrics indicate that it is reliable and using the second when the metrics indicate that the first period is unreliable. Harada teaches a method of analyzing biosignals comprising evaluating the reliability of a first calculated result, and, based on that reliability determination, deciding whether to use the first calculated result or a second one (column 3, lines 44-48; column 5, lines 17-20), in order to minimize the number of required processing steps.

The rejection of claims 1, 3-5, 7-11, and 13 under 35 U.S.C. § 103(a) is defective because the cited references in combination do not disclose all the limitations of the rejected claims.

Neither the Baker reference nor the Harada reference discloses a method or system in which a first and second heart rate may be determined by a first and second method, whereby an evaluator determines the reliability of the first heart rate, and whereby the first heart rate is used when it is reliable and the second heart rate is used when the first heart rate is unreliable.

As noted by the Examiner, the Baker reference fails to disclose an evaluator or evaluating step for using the first heart rate (claims 1 and 5) or first pulse period (claims 8 and 11) determined by the first method if it is reliable and using the second rate (claims 1 and 5) or

second pulse period (claims 8 and 11) determined by the second method only if the first is unreliable. The Examiner maintains that this defect is corrected by the Harada reference. The Applicant traverses this characterization of Harada. Harada relates to a method for calculating a blood pressure from a blood pressure cuff when a blood pressure cuff is being inflated and, only when the blood pressure is determined to be abnormal is a second blood pressure determined while the cuff is being deflated. Harada's method for determining the first value and the second value of the blood pressure is a single method. That is, Harada only discloses using one method to determine two different values of blood pressure by applying that method to different periods of the same signal. Harada does not disclose or suggest an evaluator or evaluating step for determining the reliability of a pulse rate determined by the first method if it is reliable and using the second rate determined by the second method only if the first is unreliable because, *inter alia*, Harada only discloses using a single method to determine blood pressure. As stated by the Examiner on page 2 of this action, applying metrics to a single method will result in an unchanging result, as the method will not change. Because Harada only applies a single method to the calculations, metrics applied to Harada's single method will not correct the deficiency of Baker.

Accordingly, the combination of Baker with Harada cannot render the Applicant's claims obvious. Therefore, the Applicant respectfully asserts that the rejections of independent claims 1, 5, 8, and 11 and corresponding dependent claims 3, 4, 7, 9, 10, and 13 under Section 103 are erroneous and should be withdrawn.

Rejection of Claims 2, 6, and 12 based on Baker in view of Leon

The rejection of claims 2, 6, and 12 under 35 U.S.C. § 103(a) is defective for at least the reasons set forth with regard to claims 1, 5, 8, and 11. Claim 2 depends from claim 1, claim 6 depends from claim 5, and claim 12 depends from claim 11. Accordingly, the Applicant respectfully asserts that the rejection of dependent claims 2, 6, and 12 under Section 103 is erroneous and should be withdrawn

Conclusion

In view of the remarks set forth above, Applicant respectfully requests reconsideration of the Examiner's rejections and allowance of all pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

General Authorization for Extensions of Time

In accordance with 37 C.F.R. § 1.136, Applicant hereby provides a general authorization to treat this and any future reply requiring an extension of time as incorporating a request therefor. Furthermore, Applicant authorizes the Commissioner to charge the appropriate fee for any extension of time to Deposit Account No. 06-1315; Order No. TYHC:0069/FLE.

Respectfully submitted,

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